

JAMES S. RICHTER

Of Counsel

(201) 874-7325 (m)

jrichter@midlige-richter.com

April 21, 2025

BY ECF

Honorable Tonianne J. Bongiovanni, U.S.M.J.
 United States District Court
 Clarkson S. Fisher Federal Building & U.S. Courthouse
 Room 6052
 402 E. State Street
 Trenton, New Jersey 08608

Re: *Arbutus Biopharma Corp. and Genevant Sciences GmbH v. Pfizer Inc. and BioNTech SE, Civil Action No. 23 CV 1876 (ZNQ) (TJB)*

Dear Judge Bongiovanni:

This firm represents Plaintiffs in the above matter, along with Quinn Emanuel Urquhart & Sullivan, LLP and Saiber LLP, co-counsel for Genevant Sciences GmbH, and Morrison & Foerster LLP, co-counsel for Arbutus Biopharma Corp. We write in opposition to Defendants' letter of April 10, 2025 (ECF No. 170).

INTRODUCTION

Defendants' letter is an egregious effort to obtain an improper litigation advantage by restricting the ability of Genevant's in-house counsel to supervise this multi-billion-dollar patent infringement litigation. In support of that effort, Defendants offer nothing other than baseless accusations—that Genevant's in-house counsel is willfully violating this Court's Stipulated Discovery Confidentiality Order ("DCO") and that Genevant's in-house and outside counsel are lying about it. Defendants go so far as to assert that they seek "discovery relating to **violations** of the [DCO]" and that they need to "investigate **the extent** of DCO violations." ECF No. 170 at 1, 3. Alleging violations of a court order is a serious charge, yet Defendants' letter cites **no evidence** of even a single potential violation.

Making matters worse, Defendants leveled these baseless allegations publicly, just two days after Plaintiffs reiterated their offer to provide a **sworn declaration** from Genevant's in-house counsel, Lindsay Androski, attesting that she has not engaged in any of the wrongful activities that Defendants allege—*i.e.*, explaining (a) that she has not made, and will not make, any business decisions in the prohibited areas of RNA vaccines and lipid nanoparticles ("LNPs"), either in her



T. 908.626.0622
 F. 908.626.0322



www.midlige-richter.com
info@midlige-richter.com



645 Martinsville Road
 Basking Ridge, NJ 07920

Honorable Tonianne J. Bongiovanni, U.S.M.J.

April 21, 2025

Page 2

role as CEO of Arbutus or in her continuing role as in-house counsel for Genevant, and (b) that Arbutus **has no current or planned products or product development or licensing programs in those areas**. At the very least, Defendants should have accepted Plaintiffs' offer to provide a declaration from Ms. Androski, rather than wasting the Court's time and resources with unsupported accusations of misconduct and attacks on Ms. Androski's integrity. If Defendants' interest was truly in protecting their business information as claimed, then the offered declaration would have provided safeguards and assurances that should have been welcomed.

Defendants offered no reason to question the veracity of Plaintiffs' representations and Ms. Androski's proffered testimony. Nevertheless, Defendants raced to court, besmirching Ms. Androski's reputation by asserting DCO violations and asserting an unsubstantiated need "to uncover the extent of any current and/or future DCO violations"—all **without any evidence**. Ms. Androski is an officer of the court and a highly decorated former Assistant U.S. Attorney. She signed an undertaking "to abide by the obligations of the [DCO] as they apply to me," including the prohibition against strategic business decisions relating to RNA vaccines or lipid nanoparticles. Defendants' unsupported accusations that she violated that undertaking have no place in this or any other court.¹

The true motivation for Defendants' actions with respect to Ms. Androski reveals itself when considered together with the prior treatment of Pete Zorn, Plaintiffs' other in-house counsel (Ms. Androski retained her role as in-house counsel for Genevant). Like Ms. Androski, Mr. Zorn serves in dual roles, one legal and one business. Unlike Ms. Androski, however, both of Mr. Zorn's roles are with Genevant, a company that **does** conduct RNA vaccine and LNP activities. Defendants previously agreed to Mr. Zorn's designation under the DCO, yet ask this Court to believe that Ms. Androski's business role with Arbutus, a company that **does not** conduct RNA vaccine or LNP activities, creates grave confidentiality concerns. Defendants' actions are a poorly disguised attempt to disrupt Plaintiffs' ability to manage this litigation.

BACKGROUND

A. The Parties Agreed To Limit The Competition Bar To RNA Vaccines And LNPs

The issue presented here is controlled by two unambiguous clauses in the DCO. **First**, Section 6.4 permits Designated In-House Counsel to review both Confidential and Highly Confidential documents so long as they sign a formal "Agreement To Be Bound By Discovery

¹ Plaintiffs are not affirmatively seeking sanctions at this time to avoid burdening the Court further and to provide Defendants with a final opportunity to withdraw their application. *See* Fed. R. Civ. P. 11; N.J. Rules Prof'l Conduct R. 3.1 (requiring reasonable nonfrivolous belief that assertions have a basis in fact); N.J. R. USDCT App. R.3 & R.5 (lawyers "will not, absent good cause, attribute ... improper conduct to other counsel"); *In re Vincenti*, 114 N.J. 275, 281-282 (1989).



Honorable Tonianne J. Bongiovanni, U.S.M.J.

April 21, 2025

Page 3

Confidentiality Order.” ECF No. 54, Ex. A. **Second**, Section 7.3 imposes a “Competition Bar,” applicable **solely to Highly Confidential documents**, under which an individual who receives access to such documents “shall not be involved in strategic business decisions (including marketing, financial, product development/design, and pricing decisions, on issues affecting competition) **relating to or relevant to RNA vaccines or lipid nanoparticles**, including the manufacture or use thereof (‘Strategic Business Decisions’).” *Id.*, § 7.3 (emphasis added).

The scope of the Competition Bar was carefully negotiated by the parties. It very intentionally does not impose an across-the-board prohibition on strategic business decisions. To the contrary, it plainly restricts only those business decisions “relating to or relevant to RNA vaccines or lipid nanoparticles.”² *Id.*

B. Ms. Androski And Her Roles At Genevant And Arbutus

Ms. Androski provides a unique combination of skills and experience: She holds two B.S. degrees from the Massachusetts Institute of Technology (one in biology), as well as J.D. and M.B.A. degrees from the University of Chicago; she is a registered patent lawyer, Chartered Financial Analyst, and member in good standing of the New York, District of Columbia, and California state bars, and the Fourth Circuit, Federal Circuit and U.S. Supreme Court bars. Her experience includes a Federal Circuit clerkship, four years as an Assistant U.S. Attorney, where she received the highest awards given by several federal agencies and was twice nominated for Attorney General’s awards (the highest award given by DOJ), six years as a trial lawyer in private practice, professorships at Duke University (finance) and U.N.C. Eshelman School of Pharmacy (drug development), and current service as a Trustee of the Massachusetts Institute of Technology. Ex. 1, Androski Decl. ¶¶ 2-12. Ms. Androski has been first chair or co-chair on nine trials, including patent and trademark infringement trials. *Id.*, ¶ 7.

In June 2024, Genevant disclosed Ms. Androski as Designated In-House Counsel pursuant to the DCO. Ex. 2 at 9. In connection with that designation, Ms. Androski signed an undertaking agreeing to “abide by the obligations of the [DCO] as they apply to me.” Ex. 3. Ms. Androski is

² Defendants’ cited cases are irrelevant because the DCO’s negotiated language controls. But they also do not support Defendants’ rush to court based on conjecture and supposition. Instead, “[t]he teaching of [Defendants’ cited case] *U.S. Steel* and its progeny is that restrictions on access to confidential documents or the activities of counsel will not be imposed absent some specific, identifiable showing and not on the basis of broad generalizations of potential harm. The notion that good cause can be shown simply by invoking the possibility of inadvertent disclosure has been rejected....” *Warner Chilcott Lab’ys Ireland Ltd. v. Impax Lab’ys, Inc.*, No. CIV. A. 08-6304 WJM, 2009 WL 3627947, at *3 (D.N.J. Oct. 29, 2009).



Honorable Tonianne J. Bongiovanni, U.S.M.J.

April 21, 2025

Page 4

one of only two in-house counsels designated by Plaintiffs as Designated In-House Counsel under the DCO and the only one with significant litigation experience.³

In February 2025, Ms. Androski was appointed CEO by the Board of Directors of Arbutus. Ex. 1, ¶ 19. Arbutus is a publicly traded, clinical-stage biotechnology company that does not currently have any commercial products. *Id.*, ¶ 15. Arbutus focuses on the development of products for treating chronic Hepatitis B Virus (cHBV). *Id.* None of Arbutus's current or planned product development or licensing programs involve RNA vaccines or LNPs. *Id.* Arbutus's lead development candidate, imdusiran, uses a GalNAc delivery system (not an LNP delivery system), and recently achieved functional cure in some patients with cHBV in a Phase 2a trial. *Id.*

In addition to now leading Arbutus's cHBV product development programs, Ms. Androski continues to serve as in-house counsel to Genevant, where she retains responsibility for managing this litigation. *Id.*, ¶¶ 13, 20. As before, all current or planned LNP development and licensing efforts are conducted solely by Genevant without any involvement from Ms. Androski or Arbutus. *Id.*, ¶ 20.

C. Defendants Rejected Any Consideration Of A Sworn Declaration From Ms. Androski And Ignored Repeated Representations Of Plaintiffs' Counsel

Shortly after Ms. Androski was appointed CEO of Arbutus, Defendants sought to revoke her designation. Ex. 4 at 9-10. Defendants' objection was and is based solely on the DCO's Competition Bar. According to Defendants, "*[a]s CEO, Ms. Androski can no longer comply with Section 7.3 of the DCO* because it prohibits any individual with access to Highly Confidential Material from participating in competitive decision-making." *Id.* (emphasis added). As noted above, however, Section 7.3 does not prohibit all forms of "competitive decision making"—it only prohibits strategic business decisions involving RNA vaccines and LNPs. Defendants identified no evidence that Ms. Androski has been or will be involved with strategic business decisions in those areas.

On *at least four occasions* thereafter, Plaintiffs represented to Defendants that Ms. Androski's role at Arbutus had nothing to do with RNA vaccines or LNPs and confirmed that Arbutus has no programs relating to RNA vaccines or LNPs. *See* Ex. 4 at 1, 5, 9; Ex. 5 at 1. Plaintiffs also addressed specific questions from Defendants regarding Ms. Androski's role in licensing, explaining that Arbutus licensed its patents to Genevant in 2018, with the result that Arbutus does not participate in licensing efforts as to RNA vaccines or LNPs. Ex. 4 at 5. Moreover, Plaintiffs explained that "[n]either Arbutus generally, nor Ms. Androski specifically, has any role in Genevant's ongoing licensing activities relating to LNP delivery technology...."

³ Defendants have six Designated In-House Counsel, two designated by Pfizer and four by BioNTech. Plaintiffs have two Designated In-House Counsel, both designated by Genevant.



Honorable Tonianne J. Bongiovanni, U.S.M.J.

April 21, 2025

Page 5

Id. Plaintiffs further represented that “neither Arbutus generally nor Ms. Androski specifically plays any role whatsoever in whether or how Genevant uses the licensed technology or Genevant’s sublicensing of the technology.” *Id.* at 1. Plaintiffs also reiterated that “[a]s before, Ms. Androski has no role in business decisions at Genevant” and “does not have strategic decision-making authority related to or relevant to RNA vaccines and/or lipid nanoparticles.” *Id.* at 2. Plaintiffs also confirmed that “Ms. Androski is not on Genevant’s Board of Directors nor has she attended a Genevant Board of Directors meeting.” *Id.*

The parties met and conferred on this and other issues on April 4. During that meeting, Plaintiffs offered to provide a sworn declaration from Ms. Androski addressing all of Defendants’ concerns. Ex. 6, Paunovich Decl., ¶ 9. On April 8, Plaintiffs sent an email reiterating their offer to provide a sworn declaration from Ms. Androski. Ex. 5 at 1; Ex. 6, ¶ 13. On that same day, to obviate the dispute and avoid burdening the Court, Plaintiffs sent a second email reiterating the information responsive to Defendants’ questions discussed during the April 4 meet and confer. Ex. 4 at 1-2; Ex. 6, ¶ 12. Defendants did not respond to either email. Ex. 6, ¶ 12-13. Instead, on April 10, Defendants chose to disregard Plaintiffs’ offers and file this application, leveling these serious allegations against Ms. Androski and outside counsel publicly, without a shred of evidence to support even a potential violation. *Id.*, ¶ 14.

ARGUMENT

Defendants’ motion argues that Ms. Androski should be prohibited from reviewing Confidential and Highly Confidential documents on the purported basis that she is engaged in prohibited Strategic Business Decisions relating to RNA vaccines or LNPs. Defendants are flat wrong. In the declaration provided herewith, Ms. Androski has sworn under penalty of perjury that there is no truth to any of it:

“I have not been and will not be involved in any Strategic Business Decisions (including marketing, financial, product development/design, and pricing decisions, on issues affecting competition) relating to or relevant to RNA vaccines or lipid nanoparticles, including the manufacture or use thereof. That is the case both in my role as CEO of Arbutus and in my role as Special Counsel to Genevant.” Ex. 1, ¶ 22.

“Arbutus does not market, sell, develop, design, price, manufacture, or use RNA vaccines or LNPs, or otherwise compete in the market for RNA vaccines or LNPs.” *Id.*, ¶ 23.

“Arbutus has no current or planned product development or licensing programs relating to RNA vaccines or LNPs.” *Id.*



Honorable Tonianne J. Bongiovanni, U.S.M.J.

April 21, 2025

Page 6

Despite all of this, which Plaintiffs' counsel has repeatedly explained, Defendants have doubled down on an outrageous campaign to remove Ms. Androski that assumes (a) Plaintiffs' outside counsel is being untruthful about Ms. Androski's role and suborning violations of the DCO and (b) Ms. Androski, a distinguished lawyer, is willfully violating the DCO that she formally signed and agreed to abide by. *See* ECF No. 170 at 1, 3 (seeking "discovery relating to *violations* of the [DCO]" and to "investigate *the extent* of DCO violations") (emphasis added). To level these unsubstantiated, false, and serious accusations without evidence, publicly, is particularly egregious because Plaintiffs confirmed multiple times, and even offered to provide a sworn declaration from Ms. Androski attesting, that she has not been and will not be engaged in prohibited Strategic Business Decisions and that she has not violated and will not violate the Competition Bar.

The documents cited in Defendants' letter do not support their position. *First*, as Ms. Androski explains in her declaration, Defendants' letter erroneously relies on documents nearly a decade old, before Arbutus licensed its patents to Genevant and ceased any business involving LNPs. Ex. 1, ¶ 29. *Second*, although Arbutus owns patents relating to RNA vaccines and LNPs, it licensed those patents to Genevant a *half-decade before* this lawsuit was filed, with the result that Arbutus does not participate in licensing efforts as to RNA vaccines or LNPs.⁴ *Id.*, ¶¶ 14, 30. *Third*, the press release discussed in Defendants' letter merely states, accurately, that Arbutus seeks to, among other things, "maximiz[e] the company's contributions to LNP delivery technology *through Genevant*," (ECF 170-1 (emphasis added)), *i.e.*, through Genevant's enforcement of infringing use of Arbutus's patented LNP delivery technology. *Id.*, ¶ 31. *Fourth*, neither Arbutus nor Ms. Androski plays a role in Genevant's marketing or sublicensing of the licensed patents, all of which is within Genevant's sole and independent control. *Id.*, ¶ 25. Much of this has long been public record and all of it is addressed in Ms. Androski's sworn declaration. *See generally* Ex. 1.

Defendants also speculate, without evidence, that Ms. Androski might be involved in Genevant's Strategic Business Decisions through the Genevant Board of Directors. But Ms. Androski is not a member of the Genevant Board of Directors, and Arbutus has no seat on the Genevant Board of Directors. *Id.*, ¶¶ 26-27. In fact, Arbutus owns only 16% of Genevant's common equity and has merely the right to have a non-voting observer attend Genevant board meetings. *Id.*, ¶ 26. And as Ms. Androski attests, she has never attended a Genevant Board of

⁴ It is irrelevant that the license excludes HBV-related applications because Arbutus's actual HBV product development programs use a delivery system that does not involve LNPs. Moreover, Arbutus has no current or planned product development or licensing programs relating to RNA vaccines or LNPs, whether for HBV or any other application. Ex. 1, ¶ 30.



Honorable Tonianne J. Bongiovanni, U.S.M.J.

April 21, 2025

Page 7

Directors meeting and is not Arbutus's designee to attend Genevant board meetings as an observer. *Id.*, ¶ 27.

At bottom, Defendants are not attempting to protect legitimate confidentiality interests, but are instead pulling out all the stops to disrupt Plaintiffs' ability to manage this litigation.⁵ Ms. Androski has deep experience with civil and patent litigation and is involved in essentially every material management and strategy decision in this litigation. *Id.*, ¶ 33. The majority of Defendants' document production, consisting of millions of pages, has been designated as Confidential or Highly Confidential, including regulatory submissions and research, pricing, sales, and finance documents. It is important for Ms. Androski to have access to those documents in her role managing this litigation, just as the six designated in-house counsel of Defendants have such access to enable their management roles. Ms. Androski's role is particularly important because Plaintiffs' only other Designated In-House Counsel, Pete Zorn, is a highly experienced corporate and transactional lawyer but he is not a litigator. *Id.*

Indeed, Defendants' actions with respect to Mr. Zorn belie any assertion that Defendants are bringing this motion in good faith to protect legitimate confidentiality concerns. Mr. Zorn serves dual executive roles at Genevant, a company that actually conducts RNA vaccine and LNP activities, one in business (as President) and the other in legal (as Chief Legal Officer). Yet Defendants agreed that Mr. Zorn would be a permitted Designated In-House Counsel under the DCO. ECF No. 54 §§ 1.4, 7.3; Ex. 7 at 2. Ms. Androski likewise now has dual executive roles, one in business (as CEO at Arbutus) and the other in legal (as Special Counsel at Genevant). But unlike Mr. Zorn, her business role does not involve RNA vaccines or LNPs because Arbutus has no such business. Ex. 1, ¶¶ 15, 23. It strains credulity to assert that while Mr. Zorn's business role at Genevant (which *is* involved in RNA vaccines and LNPs) creates no concern for Defendants, Ms. Androski's additional business role at Arbutus (which is *not* involved in RNA vaccines and LNPs) gives rise to Defendants' allegedly grave concerns.⁶

⁵ Defendants' request to depose Ms. Androski should be rejected out of hand; it is an admission that Defendants have no evidence of wrongdoing. *See Recchia v. Kellogg Co.*, No. CIV. 10-4899-JEI-KMW, 2012 WL 762445, at *6 (D.N.J. Mar. 6, 2012) (denying motion to compel deposition of counsel as it would intrude on the attorney-client relationship and harm plaintiff's representational rights).

⁶ Even if every baseless accusation in Defendants' letter were true, there would still be no grounds to restrict Ms. Androski's access to Confidential documents (as distinct from Highly Confidential documents). The DCO has two tiers—Highly Confidential and Confidential. The Competition Bar only applies to the Highly Confidential tier. Because the Competition Bar is the sole basis for any of Defendants' arguments, Ms. Androski should in any case remain entitled to review Confidential documents.



Honorable Tonianne J. Bongiovanni, U.S.M.J.

April 21, 2025
Page 8

CONCLUSION

Defendants are improperly seizing upon Ms. Androski's additional role as CEO of Arbutus to level baseless allegations solely designed for the purpose of prejudicing Plaintiffs' management of this litigation. Their motion should be denied.

Respectfully submitted,

s/ James S. Richter

James S. Richter

Cc: All Counsel of Record (by ECF)

